WELCOME TO THE ATLANTA VA HEALTH CARE SYSTEM

This presentation will provide you with the Atlanta VA Health Care System policies and step-by-step procedures for conducting human subject's research.

The Atlanta VA Human Research Protection Program has the infrastructure for conducting research that ensures consistency in quality and performance which is in accordance with federal regulations and institutional policies.

ATLANTA VA RESEARCH WEB SITES

Foundation for Atlanta Veterans Education and Research, Inc
https://faver.foundation.org

Research Credentialing and Training
https://www.atlanta.va.gov/services/research/Research_Credentialing.asp

Conducting Human Research
http://www.atlanta.va.gov/services/research/Conducting_Human_Research.asp

AVAHCS Website
http://www.atlanta.va.gov/ATLANTA/services/research/about.asp

Investigators Forms and Policies
http://www.atlanta.va.gov/services/research/investigators.asp

Data Analytics Core
https://www.atlanta.va.gov/services/research/Data_Analytics_Core.asp

Research Staff Must be Knowledgeable about the Guidance Documents, Tools, Policies, and Procedures Located on the AVAHCS Research Websites

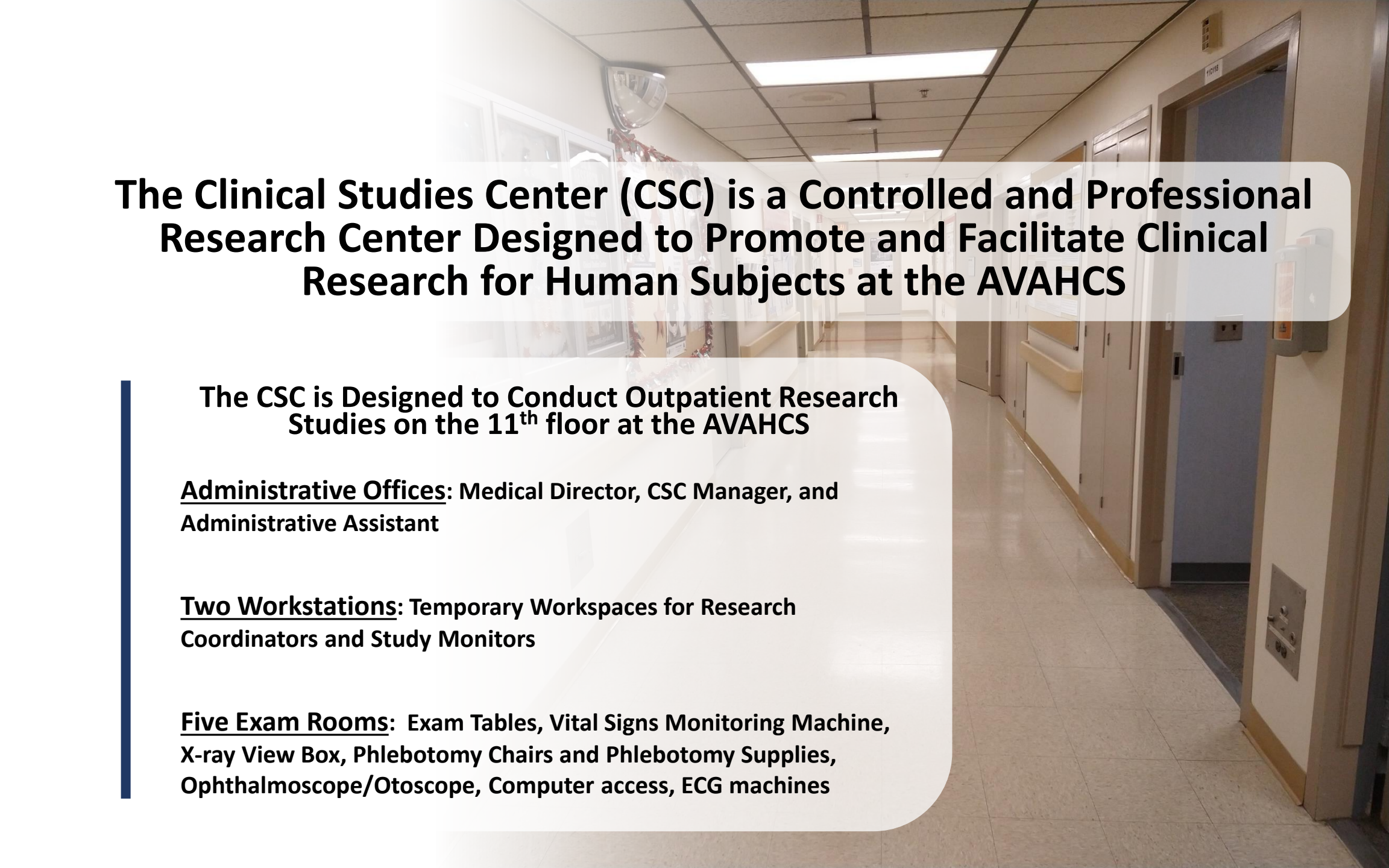
GOVERNMENT AGENCIES

- **Emory IRB Web Page** www.irb.emory.edu
- **National Institute of Health (NIH)**
  www.nih.gov
- **Office of Research Oversight (ORO)**
  www.va.gov/oro/
- **Food and Drug Administration (FDA)**
  www.fda.gov
- **Collaborative IRB Training Initiative (CITI)**
  www.citiprogram.org
- **Office of Human Research Protection (OHRP)**
  www.hhs.gov/ohrp/
- 45 CFR 50 Protection of Human Subjects:
  www.gpoaccess.gov/cfr/index.htm

PROFESSIONAL ORGANIZATIONS

- **Society of Clinical Research Associates (SOCRA)** www.socra.org
- **Association of Clinical Research Professionals (ACRP)** www.acrpnet.org
- **Public Responsibilities in Medicine and Research (PRIM&R)** www.primr.org

The Clinical Studies Center (CSC) is a Controlled and Professional Research Center Designed to Promote and Facilitate Clinical Research for Human Subjects at the AVAHCS



The CSC is Designed to Conduct Outpatient Research Studies on the 11th floor at the AVAHCS

Administrative Offices: Medical Director, CSC Manager, and Administrative Assistant

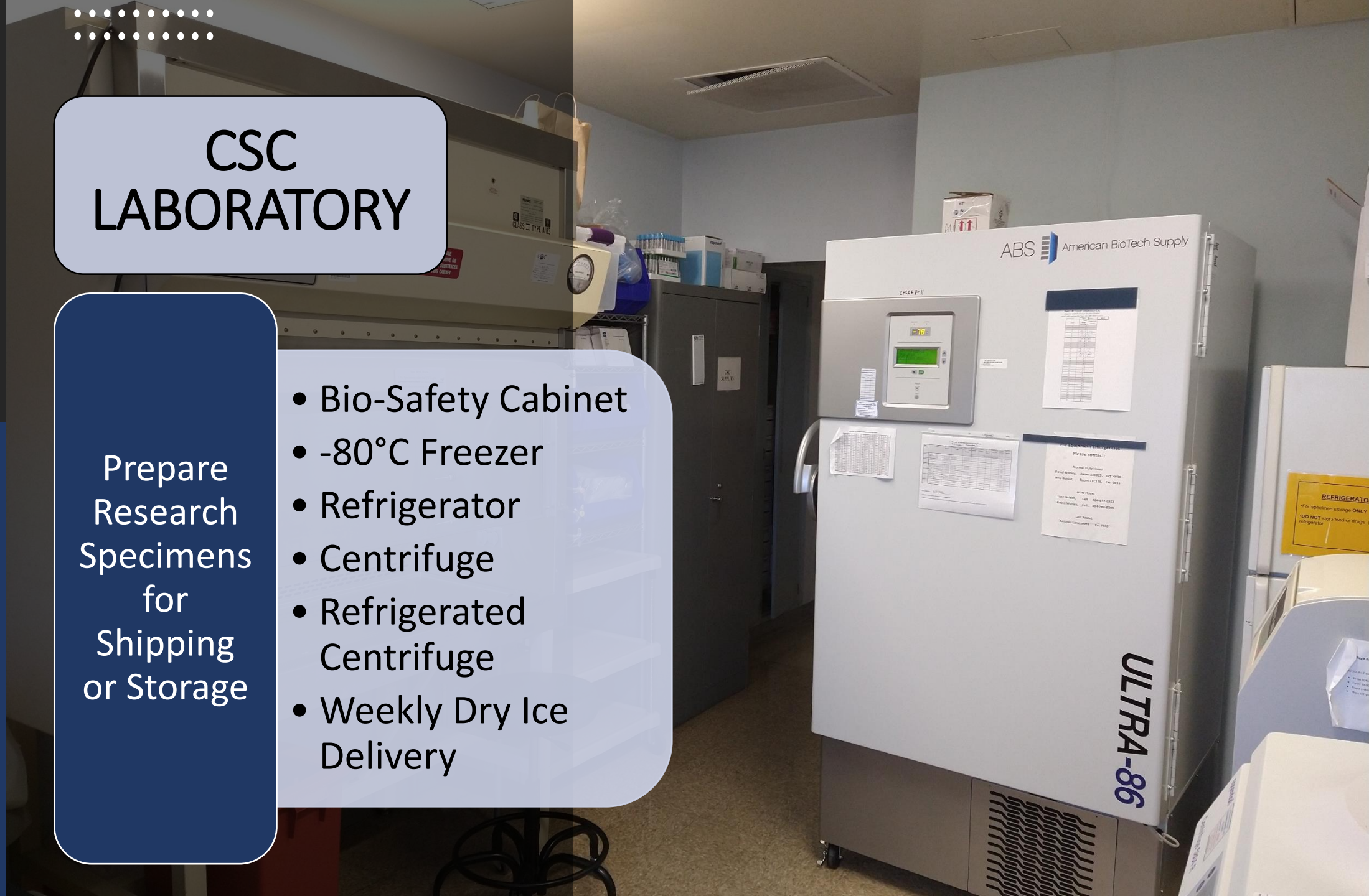
Two Workstations: Temporary Workspaces for Research Coordinators and Study Monitors

Five Exam Rooms: Exam Tables, Vital Signs Monitoring Machine, X-ray View Box, Phlebotomy Chairs and Phlebotomy Supplies, Ophthalmoscope/Otoscope, Computer access, ECG machines

CSC LABORATORY

Prepare Research Specimens for Shipping or Storage

- Bio-Safety Cabinet
- -80°C Freezer
- Refrigerator
- Centrifuge
- Refrigerated Centrifuge
- Weekly Dry Ice Delivery

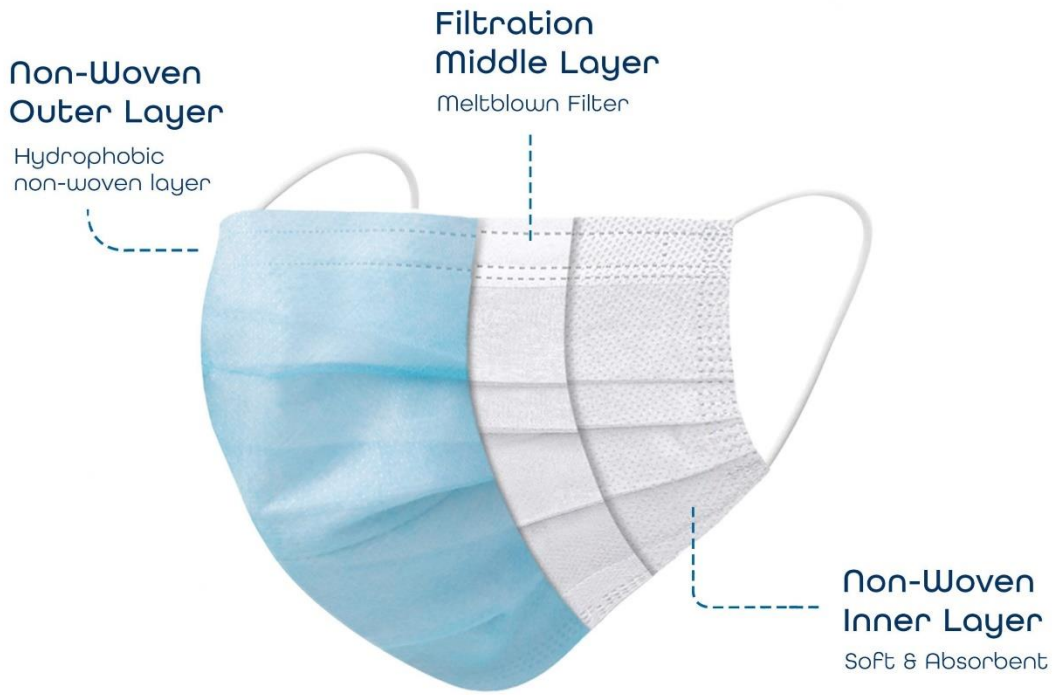


To Reserve an Exam or Interview Room at the CSC, submit a request through the [CSC Rooms Request Form]

Study Staff are Responsible for Greeting Participants in a Timely Manner and Notifying the CSC of Appointment Cancellations


[1] WEAR A
FACE MASK

3-Layer Filtration



viewPDF.cfm (va.gov)

Principal Investigator Oversight

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Atlanta VA Health Care System

Delegation of Responsibilities to Qualified Staff

GCP 4.2.3, GCP 4.1.5

Medical Oversight of Study Subjects

GCP 4.3.14, GCP 4.3.2

Delegation of Responsibilities to Adequately Trained Staff

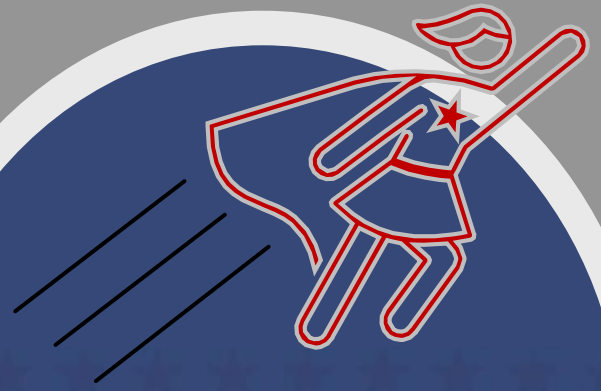
GCP 4.2.4, ICH GCP Aden 4.2.6

Adequate Supervision and Involvement

21CFR 312.30, GCP 4.2.2, FDA Guidance Document

Research Staff

- Study Drugs
- Training
- Sponsor Meetings
- Protocol
- Federal and Institutional Policy
- Regulatory Documents
- Reportable Events
- Screening and Recruitment
- Privacy Rule (21CFR)
- Study Documents (CPRS, CRF, Source)
- Consent and HIPAA
- Patient Safety
- IRB and R&D



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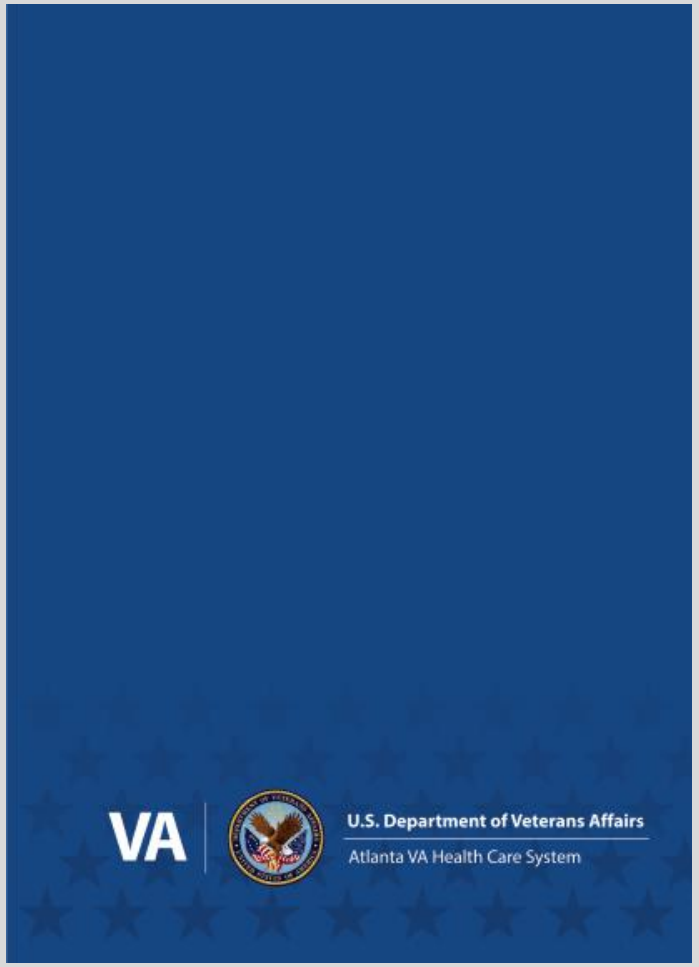
Atlanta VA Health Care System

Staff Credentialing & Training Requirements



In order to be engaged in research at the AVAHCS, Investigator and Co-Investigators must either have a VA appointment or without compensation appointment (WOC).

All MDs, RNs, LPNs, LCSWs, and other licensed personnel must complete VetPro credentialing prior to engaging with research subjects.

Additional Certification and Training

Phlebotomy Certification

CSC Laboratory Access

Notify the CSC Manager if additional Certification or Training is needed

Where are Your Research Data Stored and Transmitted?

IRB and **R&D Approvals**

Protocol - Data Management & Security Plan

Research Data Inventory Form

IRB and **VA Applications**

These Documents Will Tell You if You are Permitted to Disclose Data and How

Data Management and Security

VA Research Data and Information Must be Saved on a Secured AVAHCS Research Server. Contact the Director of Research Operations for Access

Secure Paper Study Files in a Locked Cabinet and a Locked Office at the VA. Never Leave PHI Unattended

All VA Sensitive Research Information Needs to be Stored within the VA Unless Approvals by Privacy and Information Systems Security Offices are Given

PHI and/or Identifying Information Should Not be Included in the CRFs Unless Special Authorization for a Limited Data Set Has Been Granted

Social Security Numbers Should Not be Recorded in the CRFs – Only Use a Study ID to Identify Study Participants

Data Outside the VA

Data Transfer Agreements and Data Use Agreements

Laptops and flash drives must be encrypted by the VA if used for transporting data outside the VA

Authority to Transport (AUT)

AUT is needed if physically transporting outside of the VA any of the following:

- Paper research files containing PHI and/or
- Specimen/samples that are labeled with code+date+other element of PHI

An AUT is not required if specimen contains only study ID and a date

New Study Approval Process

Safety Subcommittees and PO/ISSO Pre-Review (IRBNet)

IRB Submission and Approval

VA R&DC (IRBNet) Submission and Approval

ACOS/R Letter

ENROLL

ACOS/R Letter

VA | U.S. Department of Veterans Affairs
Atlanta VA Health Care System

DEPARTMENT OF VETERANS AFFAIRS
Atlanta VA Health Care System R&DC
Atlanta VA Health Care System

Date:	**April 21, 2021**
From:	ACOS/R&D and R&D Committee
TO:	**April Maa, MD**
Protocol Title:	**[1618546-1] Genetic Risk for AMD in Diverse Veteran Populations**
Submission Type:	**New Project**
Review Type:	**Full Committee Review**
Action:	Combined Associate Chief of Staff for Research and Development (ACOS/R&D) and R&D Committee Study Approval Notice

1. This research project was reviewed and found to be aligned with the mission of the VHA, scientifically valid, and reviewed by all appropriate subcommittees to ensure the safety of the study subjects and VHA staff. Approval is granted by **CONVENED BOARD REVIEW** of the Atlanta VA Health Care System Research and Development Committee.
2. This research project has obtained the following additional approvals:
    a. VA Central Institutional Review Board Approval: PI/SC 08/08/2016 LSI 02/18/2021
3. The Privacy Officer reviewed this research project on 07/13/2016 and found that the proposed research complies with VA Privacy Requirements.
4. The Information Safety and Security Officer reviewed this research project on 07/19/2016 and found that the research project complies with information safety and security requirements for VA.
5. A waiver of HIPAA authorization was approved by the VA Central IRB on 08/08/2016.
6. You are responsible to your overseeing committee for any requests for information, continuing review (if required), or other project status updates. No changes may be made to your project without the permission of the reviewing subcommittee unless there is a circumstance where harm could come to a research subject. Immediate reporting to the responsible committee is then required.
7. If any of your personal or financial situations change that may reasonably put you in conflict with this study, you must submit a revised OGE 450 Alt to your local conflict of interest administrator.
8. Acknowledgment of the VA's contribution is required in any publications and presentations that may result from this research.
9. As all applicable approvals have been obtained, you may now begin your research project.

Charles M. Hart 992390
Digitally signed by Charles M. Hart 992390
Date: 2021.04.22 16:14:12 -04'00'

Associated Chief of Staff for Research and Development (ACOS/R&D)

A study can be closed when

- Enrollment is closed and all subjects have completed study participation
- Data collection is completed. No additional PHI is being collected
- Collection of specimens has ceased
- The sponsor terminates the study and completes a study close out visit
- Data analysis of PHI is complete

Retention Schedule January 2020 Chapter 8 – Office of Research and Development

Study Closeout and Record Storage

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Atlanta VA Health Care System

Amendments and Continuing Reviews

ALL CHANGES TO THE ORIGINALLY APPROVED STUDY MUST BE REVIEWED BY THE IRB

Submit Staff Changes to eRRRP
Submit Staff Changes to eIRB for Emory Studies

REQUIRED R&D APPROVAL

- Risk/Benefit Ratio
- Change in PI
- Amendment to a Data Repository

CONTINUING REVIEW

Required by the IRB Based on the Degree of Risk

Set an Outlook Reminder 30 Days Before Expiration

Avoid Lapses

RECRUITMENT

These Policies Must be Followed when Recruiting Potential Research Subjects at the AVAHCS

- Recruitment Policy
- In Person Recruitment Policy
- Recruitment Flyer Policy
- Recruitment policies for Non-VA research projects

CONTACTING POTENTIAL PARTICIPANTS

You May Make Initial Contact with Potential Subjects:

- In Person
- IRB Approved Recruitment Letter
- IRB Approved and Encrypted Email
- Through a Registry

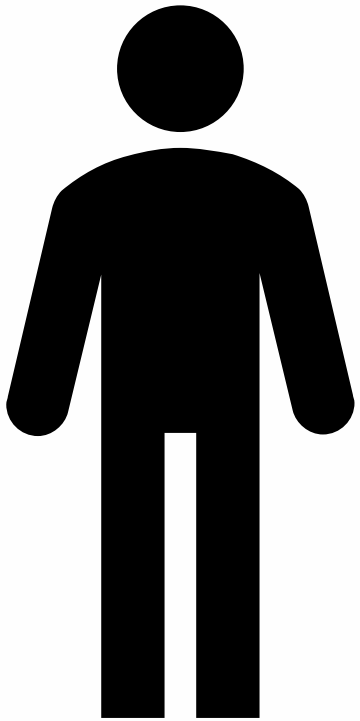
CONTACTING POTENTIAL PARTICIPANTS

Share the AVAHCS RCO phone number - (404) 321-6111 ext. 206964

Participation is **VOLUNTARY**

Safeguard Against Coercion

RECRUITMENT LETTERS



- Equal Opportunity to Opt-in or Opt-out
- Keep It Confidential
- Use Official VA Letterhead
- Name the Referring Provider
- Contact Information for AVAHCS Research Compliance Officer

Date: May 21, 2021

Joan R. Patient
29 High Glucose Street
Atlanta, GA 30033

Dear Ms. Patient,
I am writing to tell you about a voluntary research study being conducted at the Atlanta VA Healthcare System by Dr. Iam Expert in the Diabetes Unit. I am letting my patients with diabetes who are under 40 years old know about this research project, in case they would like to participate.

Dr. Expert is studying environmental causes and effects of diabetes. Diabetes may run in certain families, but many other things like diet and exercise can influence a person's risk of developing this disorder. This research project is designed to find out whether diabetes in some people can be linked to specific genes.

The researchers are looking for patients under 40 years old, with diabetes, who have a brother or sister who also has diabetes. Participation would involve two visits to the Clinical Studies Center at the Atlanta VA Medical Center, each lasting about half a day. There are no medications involved. Participation includes a dietary evaluation, questionnaires, a medical and family history, a physical exam by a study doctor and blood and urine tests.

You will not receive any personal health benefits because of your participation in this research study. We hope that the results will help us understand diabetes better, and will benefit patients with diabetes in the future. Your participation in this research study is voluntary. Whether you participate or not will have no effect on the medical care or benefits that you receive at the Atlanta VA Healthcare System.

If you would like more information about the study, please contact the study coordinator Jane Helper, RN, at (404) 321-6111-XXXXXX or Dr. Expert at (404) 321-XXXXXX. You may also return the attached letter and check the box to indicate if you do or do not want to participate in this research study. You may return the letter enclosed in the postage paid addressed letter provided. If we haven't heard from you in 2 weeks, someone from Dr. Expert's research team may phone you.

The Atlanta VA Research Compliance Officer (RCO):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the Atlanta VA RCO at: (404) 321-6111 ext. 206964.

Thank you in advance for considering this request.

Sincerely,

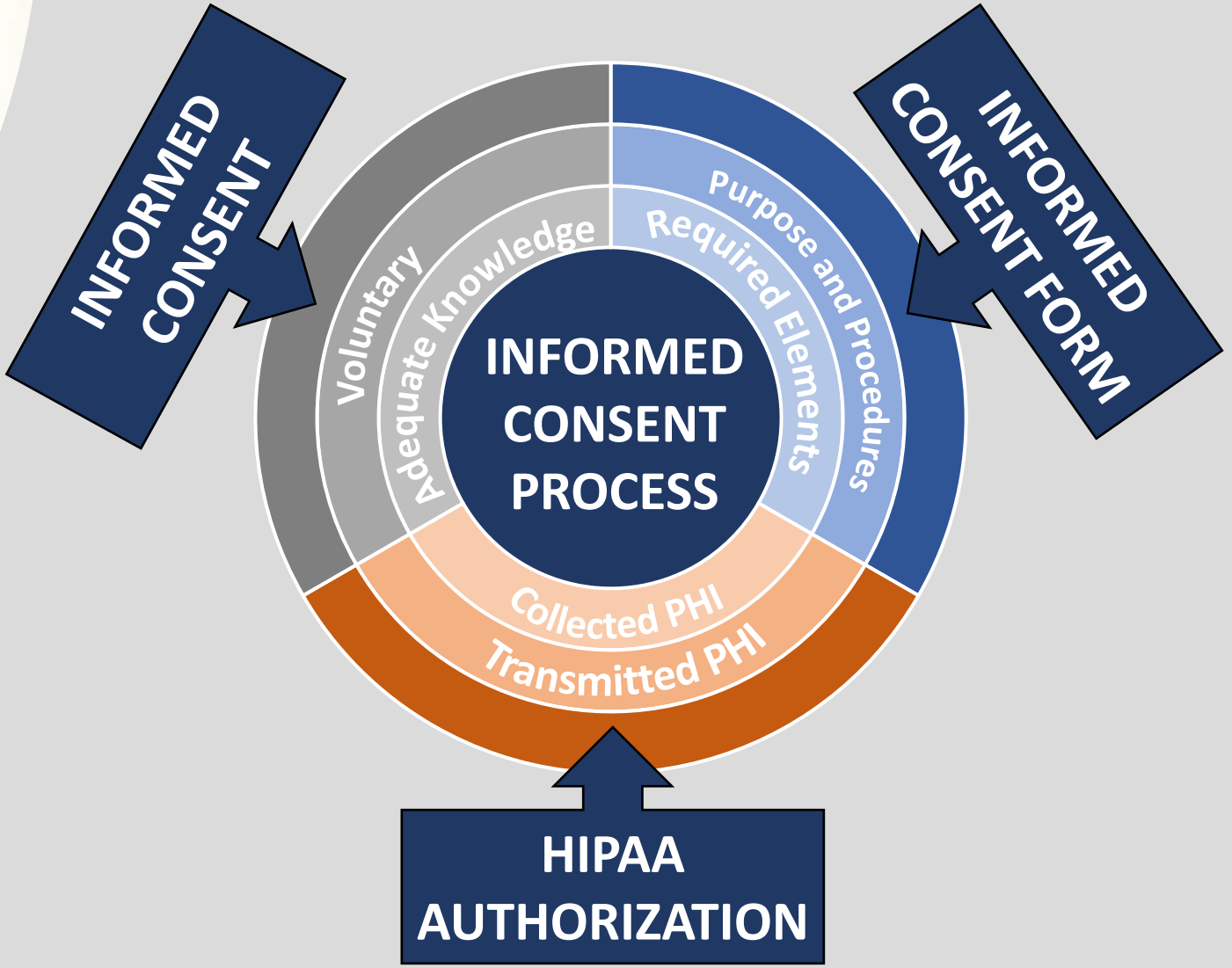
Primary Care Physician, MD
(XXX) XXX-XXXX
Note: May also be a clinician or specialist well-known to patient but must not be a member of the research team.

Iam A. Expert, MD
Diabetes Research Unit
(XXX) XXX-XXXX

Include enclosure(s) as applicable:Opt-in/Opt-Out Form, Recruitment materials, e.g. brochure, flyers, etc.

7/20/2018


INFORMED
CONSENT
Signature

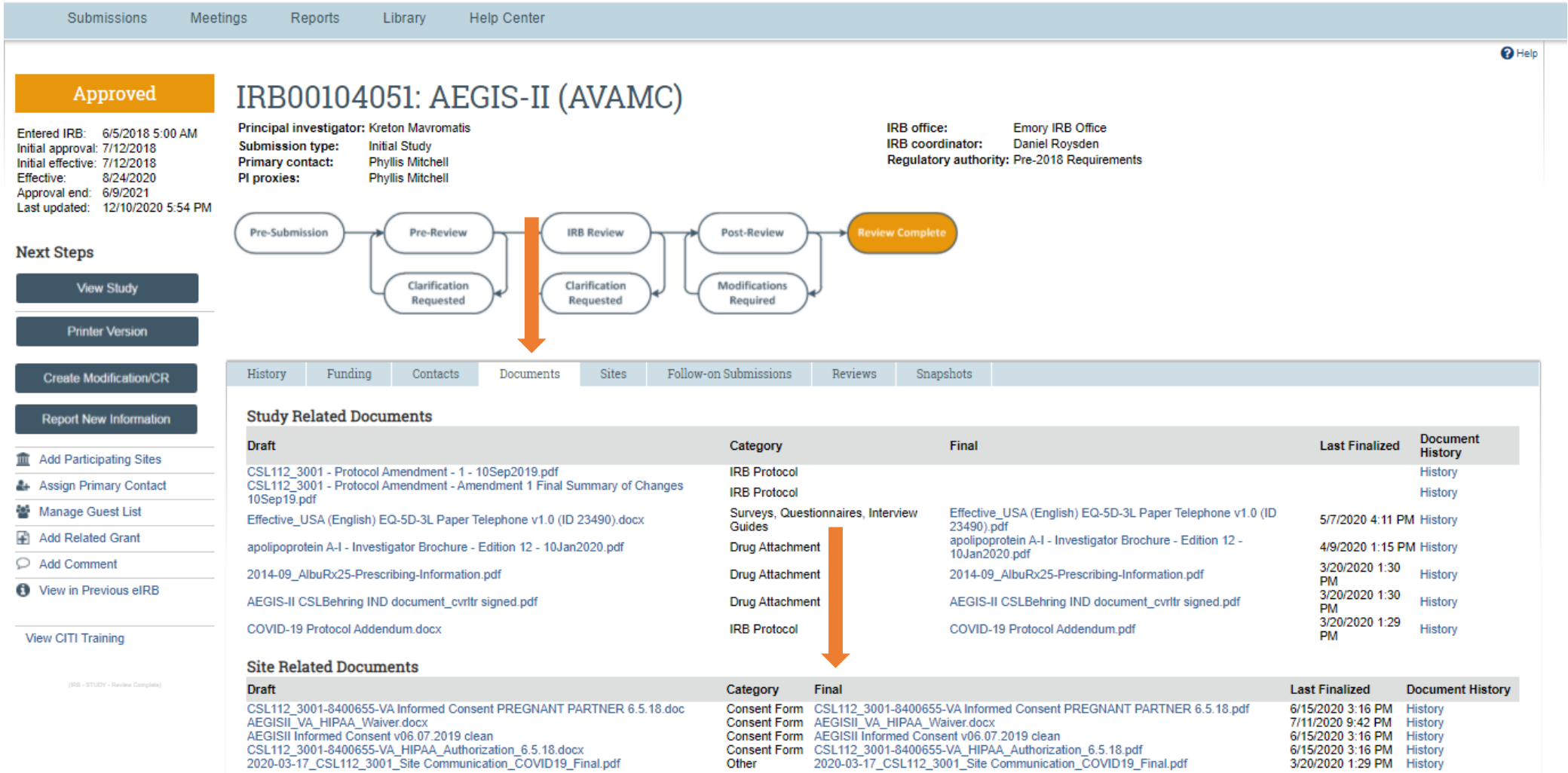

INFORMED CONSENT
INFORMED CONSENT FORM
Voluntary
Adequate Knowledge
Purpose and Procedures
Required Elements
INFORMED CONSENT PROCESS
Collected PHI
Transmitted PHI
HIPAA AUTHORIZATION

Consent

Best Practices

- Obtain Informed Consent and HIPAA **PRIOR to Initiating Any Study Activity**
- Use a Private Room
- Most Current, IRB Approved Versions of the ICF and HIPAA
- Discuss All Elements of the Consent
- Answer All Questions from the Subject
- Allow Subjects Sufficient Time for Review of ICF
- May Provide a Copy of the ICF to the Potential Study Participant Prior to a Scheduled Discussion (mail, email, in person)

The Informed Consent Process



Must use Final version and not Draft

ICF Signature Page

- Subject (or LAR) Must Print Name, Sign, and Enter the Date. Study Staff are NOT permitted to complete any fields for the Subject
- Marks are acceptable in situations where the subject has difficulty signing
- The VA does not require a POC signature, but many sponsors require it

Standalone HIPAA – VA form 10-0493

- Staff Must complete the header on each page.
- All subjects or LAR must sign and date page 4
- Page 5 is Signed ONLY if applicable (when optional data or biological specimens are being placed in a repository).
- Do not complete or enter information on page 5 if it is not applicable. It may be removed if not being used.

HIPAA AUTHORIZATION

- To whom the PHI is Disclosed
- Description of Purpose for the Disclosure
- Expiration Date for the Disclosure
- Patient Rights to Revoke Authorization
- Signature of Subject or Legal Representative
- Authorization For Specimen or Data Repository


Provide a Copy of ICF to the Subject
Keep Original ICF and HIPAA with Investigator's Files
Document Consent in CPRS or Paper Chart

If there is any question about a potential subject's decision-making capacity and there is no documentation in the medical record that the individual lacks decision-making capacity and the individual has not been ruled incompetent by a court of law, the investigator must consult with a qualified practitioner (can be on the research team) about the individual's decision-making capacity before consenting

Legally Authorized Representative (LAR)

- Individuals that may serve as LARs are (in this order):
  - Health Care Agent (Durable Power Of Attorney for healthcare)
  - Legal guardian
  - Next-of-kin (relative)
  - 18 years of age or older in the following order 1- spouse, 2- child, 3- parent, 4- sibling, 5- grandparent, 6- grandchild
  - Close friend

A Personal Representative may sign the HIPAA on behalf of a subject

- The subject's Health Care Power of Attorney (POA)
  - Court Appointed Legal Guardian

LARs May be Qualified to Sign ICF but Are Not Always Qualified to Sign the HIPAA

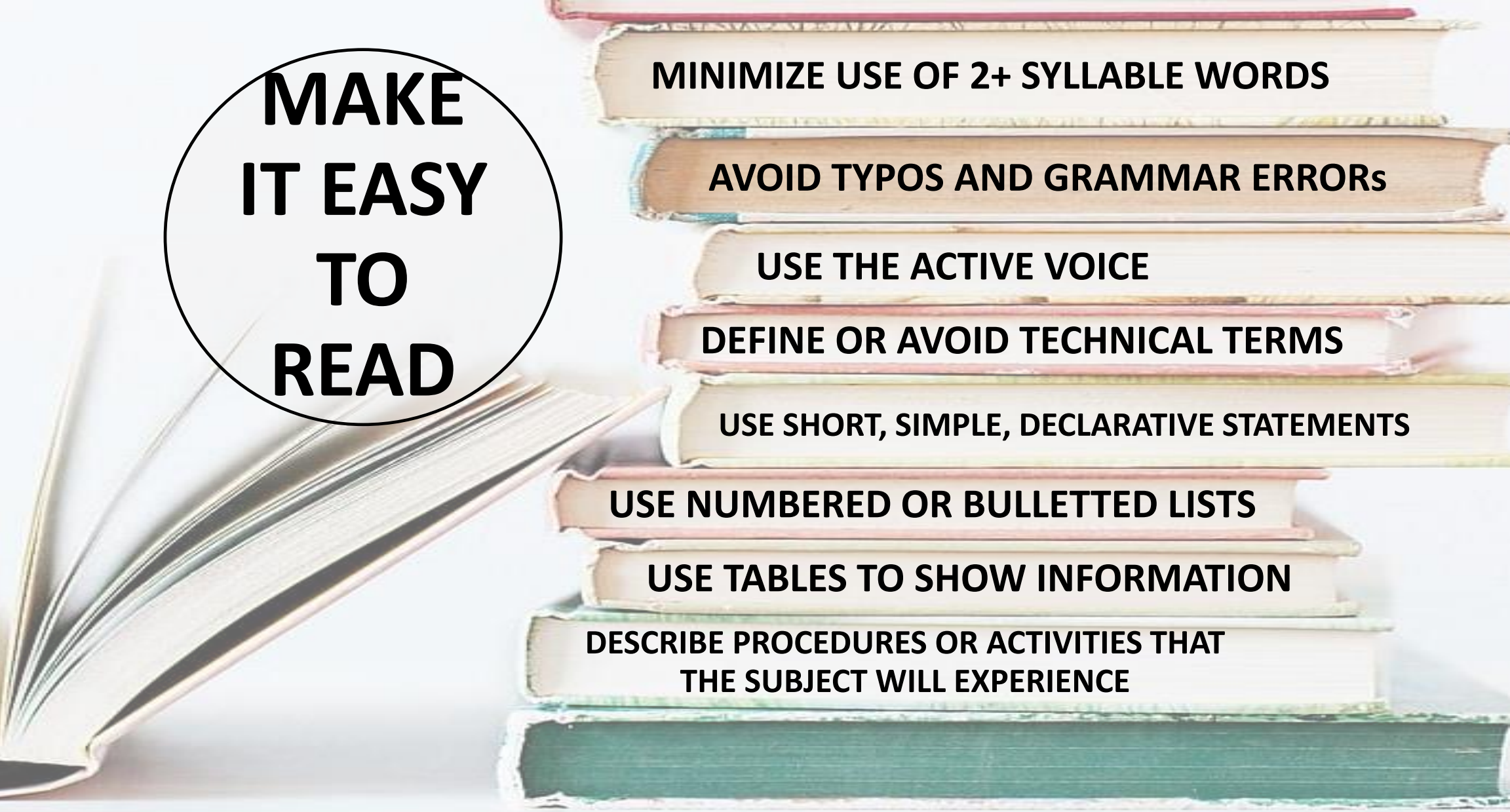
Consent Form Templates

- VA Informed Consent Form template – pre-2018 Common Rule
- VA Informed Consent Form & HIPAA template *combined* – 2018 Common Rule
  - Study must not include optional tissue/data banking or use of LAR
- VA Informed Consent Form *Standalone* – 2018 Common Rule
  - For studies that include optional tissue/data banking or use of LAR
- VA Form 10-0493 *Standalone* HIPAA
  - Must be used if using a standalone ICF

National Cancer Institute Template for Oncology Studies

CIRB Template for VA CIRB Studies

MAKE IT EASY TO READ



- MINIMIZE USE OF 2+ SYLLABLE WORDS
- AVOID TYPOS AND GRAMMAR ERRORs
- USE THE ACTIVE VOICE
- DEFINE OR AVOID TECHNICAL TERMS
- USE SHORT, SIMPLE, DECLARATIVE STATEMENTS
- USE NUMBERED OR BULLETTED LISTS
- USE TABLES TO SHOW INFORMATION
- DESCRIBE PROCEDURES OR ACTIVITIES THAT THE SUBJECT WILL EXPERIENCE

NOTICE OF PRIVACY PRACTICE

Required for Any Non-Veteran Enrolling in a AVAHCS Study

Review the NOPP Policy on the Conducting Human Research Website

HIPAA Waivers & Alterations

Privacy Rule Allows the Use and Disclosure of PHI Without a Patient's Authorization

- Solely in Preparation of Research
- IRB Approved
- PHI is Necessary to Conduct the Research

HIPAA Alteration Worksheet

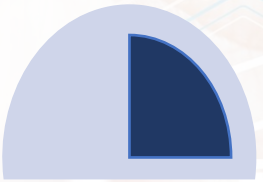
Required at initial submission

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of

HIPAA WAIVERS

Research activities are not considered to be part of normal healthcare operations and therefore a HIPAA waiver and/or signed HIPAA authorization is required

Partial Wavers



A partial HIPAA waiver permits the use of PHI for recruitment purposes only, to allow identification and, as appropriate, contact of potential participants to determine their interest in study participation

Full Waivers

A complete HIPAA waiver allows an investigator to use and disclose PHI for a particular research trial or activity without obtaining written authorization from the participants

List of PHI

(Protected Health Information)

- Names
- Dates
- Addresses / Zip Codes / Geocodes
- Phone Numbers
- Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate /License Numbers
- Device Identifiers
- Vehicle Identifiers
- URLs
- IP Addresses
- Biometric Identifiers
- Facial Images
- Any Other Unique Identifiers

SUBPOENA

CERTIFICATE OF CONFIDENTIALITY

PROTECTION AGAINST COMPULSORY LEGAL DEMANDS FOR PHI

COURT ORDER

RESEARCH COMPLIANCE OFFICE

HIPAA AUTHORIZATON

Correct Version
Signed and Dated

CONSENT FORM

Correct Version
IRB Stamp
Subjects Print, Signed, and Dated.

CPRS

Consent Visit Documentation

MONITORING AND SPONSOR VISITS

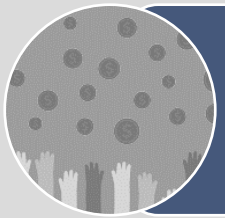
- ✓ All Monitors Check in at CSC
- ✓ Restricted Access to PHI

- ✓ CPRS Driver Method
- ✓ Immediately Report Non-Compliance

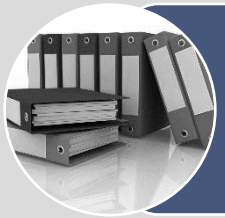
Research Subject Reimbursement

Undue Pressure or Coercion

Consenting



Reimbursement Procedures Depend on Where the Funds are Managed (VA, Emory, FAVER)



Maintain Clear Documentation of All Subject Reimbursement

REGULATORY DOCUMENTATION

Protocol and any amended protocols	IRB & R&D approval documentation	Copies of the eIRB initial submission	Copies of the eRRRP submission
Approval letter from ACOS for Research	Approved Informed Consent Form and HIPAA Documents	Modifications forms with supporting documents	Continuing review approval documentation
Reportable Events (SAEs, UPs, SPs, RIIs)	Recruitment materials	IRB, R&D, and Sponsor's Correspondence	Protocol Termination form
Investigator's Brochure	Final signed 1572 and amended FDA 1572s	Principal Investigator's CV	Copy of randomization codes
Investigational article log and copies of drug/device shipment/retrieval	Lab Certification	Accounting of Disclosure Form	Enrollment log
Monitoring visits reports	Research Training Certification	Signature and Delegated Responsibilities Log	Abstracts or manuscripts with study results

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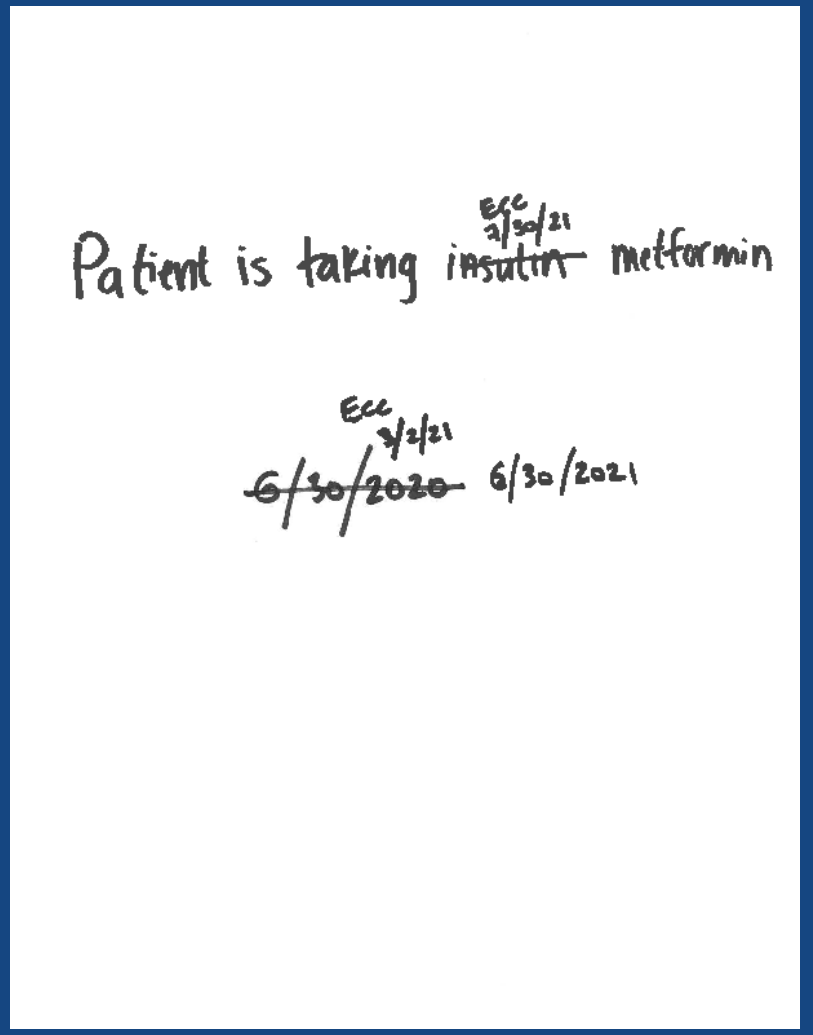
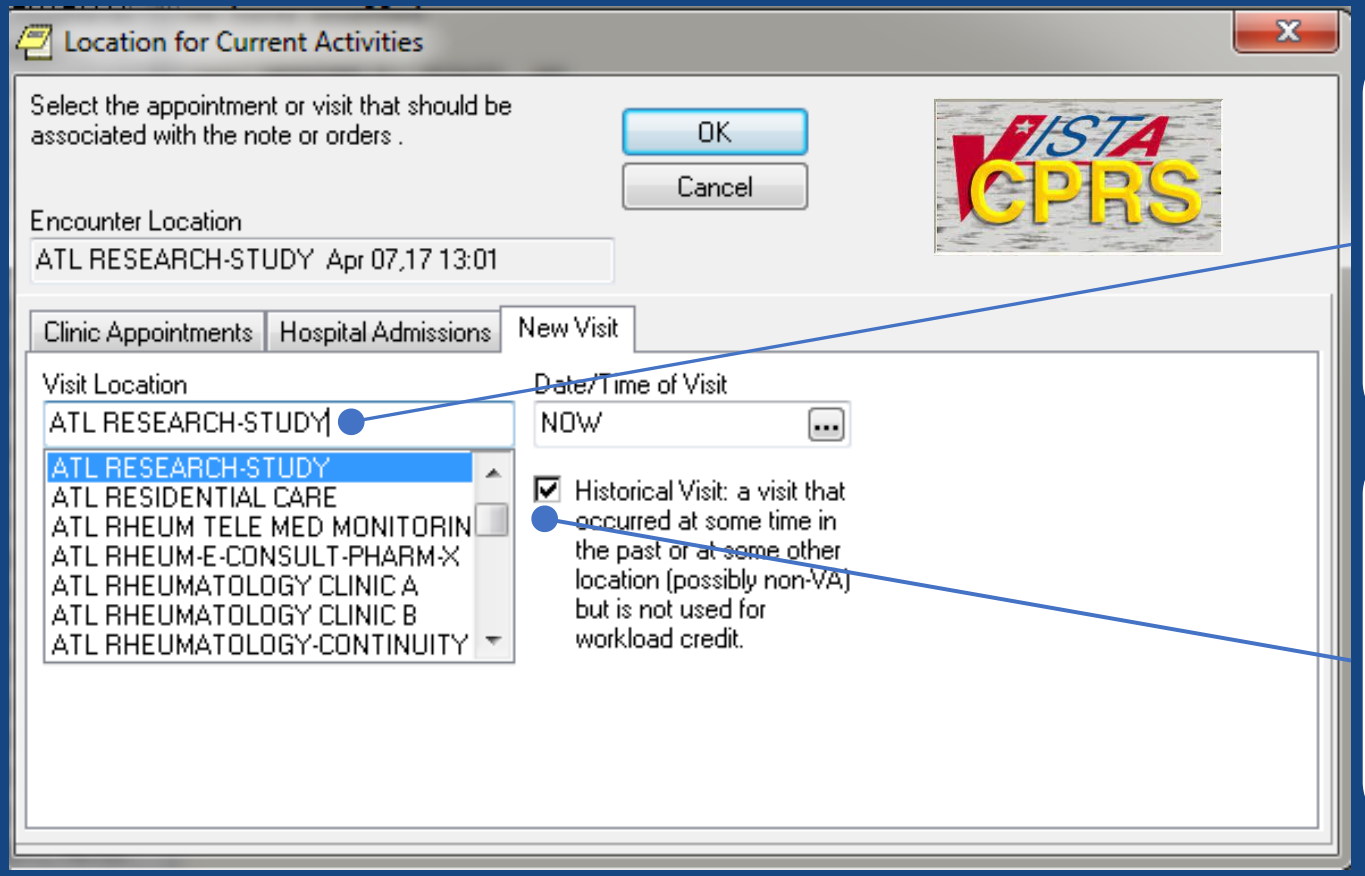
Documentation

Source Documents

Documentation
Source Documents



CPRS NOTES



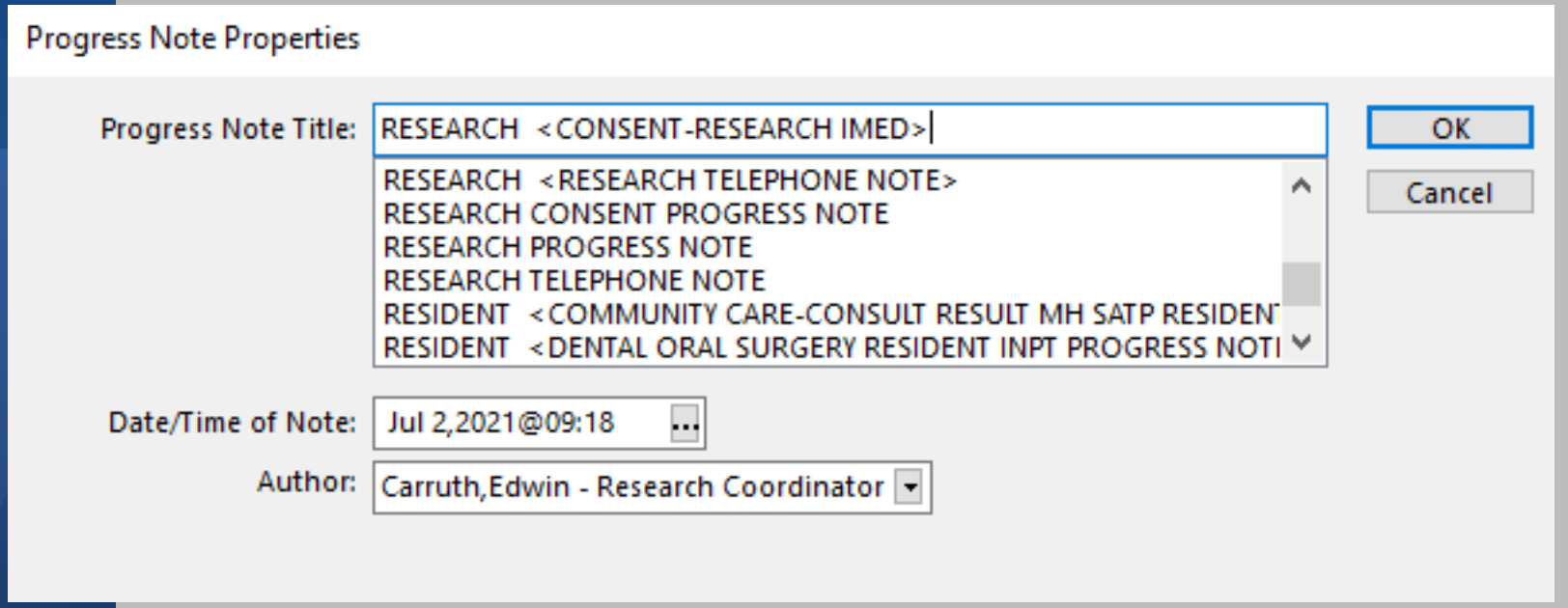
Visit Location

- **<u>ALWAYS</u> select "ATL Research-Study or other ATL Research-Clinic**

Historical Visit

- **<u>ALWAYS</u> select Historical Visit**

CPRS NOTES


Progress Note Properties
Progress Note Title:
RESEARCH <CONSENT-RESEARCH IMED>
RESEARCH <RESEARCH TELEPHONE NOTE>
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RESIDENT <COMMUNITY CARE-CONSULT RESULT MH SATP RESIDEN
RESIDENT <DENTAL ORAL SURGERY RESIDENT INPT PROGRESS NOTI
OK
Cancel
Date/Time of Note:
Jul 2,2021@09:18
Author:
Carruth,Edwin - Research Coordinator

	A	B	C	D	E	F	G	H	I
1	**Accounting of Disclosures Form for Research**								
2	**Department Name:** Research **P.I.** Dr. Cherry Wongtrakool - Exhale Study - ext. 4183								
3	Patient Name	Last four SS#	Date of Disclosure	Description of what was disclosed/sent	Purpose of Disclosure	Employee who disclosed info	How info was disclosed	Name of Outside Person, Title & Organization	Address and Phone# of Person or Outside Organization
4	John Smith (alias)	(2222)	2.1.12 and 3.1.12	ICF, CRFs, labs, med hx	research	Jane Guidot	electronic data entry and fax	1) **NIH** - Dr. Bob Lee, PI 2) **ICON Lab** - Betty Smith, monitor	1)**NIH**= 123 Baltimore MD 55022 . 444 444-6666, 2) **ICON** Lab 123 Oak St. St Paul , MN 55082 555 666-7777
5	Jane Doe (alias)	(1234)	1.1.12, 1.13.12, 1.15.12, and 2.31.12	study visit 1 and 2 and queries	see above	Jane Guidot	electronic data entry	see above	see above

Accounting of Disclosures

SCANNING PROCEDURES

VA Form 10-9012 – Investigational Drug Information Record

VA Form 10-0483 – Notice of Privacy Practices Acknowledgement

VA | U.S. Department of Veterans Affairs
Atlanta VA Health Care System

Unanticipated Problem in Human Subject's Research Involving Risks to Subjects or Others (UPIRTSO)

REPORTABLE EVENTS

UNANTICIPATED/UNEXPECTED

Refers to an incident, experience, or outcome in human research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population.

RELATED TO RESEARCH

The phrase related to participation in the research" means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome. The phrase "possibly related to participation in the research" implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.

REPORTABLE EVENTS

SERIOUS ADVERSE EVENT (SAE)

An untoward occurrence, whether or not considered related to a subject's participating in research, that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

SERIOUS PROBLEM (SP)

1. A problem in human research that may reasonably be regarded as:
2. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
3. Substantively compromising a facility's human research protection or human research oversite programs. (VHA Handbook 1058.01§4t)

PROTOCOL DEVIATIONS

A departure from the IRB-approved protocol. Deviations may represent minor departures and/or noncompliance.

- Report PDs to the IRB of record if there has been a substantive deviation from the protocol that could or did adversely affect at least one of the following:
  - The rights, welfare, or safety of subjects;
  - The subject's willingness to continue participation; or
  - The scientific integrity of research data
- Protocol Deviation and Noncompliance Policy is located on the AVAHCS research website.

NON-COMPLIANCE

Definition "Failure to comply with any of the regulations and policies of the IRB and/or VA and failure to follow the determinations of the IRB and R&D Committee"

- Noncompliance may be minor or sporadic, or it may be serious and/or continuing
- Noncompliance can be on the part of researchers, staff, other employees, and of the IRB

<u>Consult the IRB or the VA Research Compliance Officer (RCO) for questions about what to report and how</u>

REPORTABLE EVENTS

VA Investigators must report to the IRB of Record and the AVAHCS Research Office all UPIRTSOs

This includes UNANTICIPATED and research RELATED

1. **Local Research Deaths**
2. **Local Serious Adverse Events (SAE)**
3. **Serious Problems (SP)**

REPORTING TIMELINES

IMMEDIATELY (WITHIN 1 HR)

Incidents, events or problems that involve the unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of **VA research-related protected health information (PHI), individually identifiable private information, or confidential information** as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act or 38 U.S.C. must be reported **within 1 hour** as described in the AVAHCS policy entitled: **"Research Information Incidents."** This policy can be found on the AVAHCS research website

In Addition to Reporting the Event to the IRB of Record, Email Must be Sent to VAReportableEvents@faver.foundation to Alert the AVAHCS Research Office that a Reportable Event has occurred. Include the following information:

- PI's name
- IRB number
- IRB name
- Study title
- Summary of the event

REPORTING TIMELINES

DATA INCIDENT

IMMEDIATELY (1hr)

Deaths

SAE & SP

5 BUSINESS DAYS

IMMEDIATELY (WITHIN 1 HR)

Deaths that are Unanticipated and Related to the Research Conducted in Local VA Studies Must be Orally and Immediately (within one hour) Reported to the IRB of Record and AVAHCS Research Office, Followed by a Written Report within 1 Business Day

In Addition to Reporting the Event to the IRB of Record, Email Must be Sent to VAReportableEvents@faver.foundation to Alert the AVAHCS Research Office that a Reportable Event has occurred. Include the following information:

- PI's name
- IRB number
- IRB name
- Study title
- Summary of the event

REPORTING TIMELINES

Immediately
(1 hr)

IMMEDIATELY
(1 hr)

5 BUSINESS DAYS

Other Unanticipated and Research Related Reportable Events Must be Reported to the IRB of Record and the AVAHCS Research Office Within 5 Business Days of Learning of the Event

In Addition to Reporting the Event to the IRB of Record, Email Must be Sent to VAReportableEvents@faver.foundation to Alert the AVAHCS Research Office that a Reportable Event has occurred. Include the following information:

- PI's name
- IRB number
- IRB name
- Study title
- Summary of the event

REPORTABLE EVENT POLICIES

The "Reportable Event Policy", the "Reportable Event Flowchart", and Other Forms and Instructions are Located on the AVAHCS Research Website

National Cancer Institute (NCI)
https://www.ncicirb.org/institutions/institution-quickguides/managing-study/completing-up-and-or-scn

Emory IRB
http://www.irb.emory.edu/forms/reportable.html

VA Central IRB
https://www.research.va.gov/programs/pride/cirb/forms/119.doc

All of Us
Report per All of Us IRB SOP 0312

REPORTABLE EVENT POLICIES

The PI may be required to submit a summary of all local reportable events at Continuing Review to the IRB of Record. If using Emory IRB, submit the "**Atlanta VA Periodic Reportable Event Summary**" posted on the AVAHCS research website.

The PI is also responsible for tracking any events that did not meet the reporting threshold and documenting why this event did not need to be reported within that time frame. Keep this information with the study records.

References

1. VA Research Policies and Procedures: https://www.atlanta.va.gov/services/research/Conducting_Human_Research.asp
2. Good Clinical Practice
3. International Committee on Harmonization
4. Code of Federal Regulations Title 21
5. CoC: https://grants.nih.gov/policy/humansubjects/coc/what-is.htm
6. VA Records Retention Schedule January 2020
7. VHA Directive 1200.05
8. Common Rule
9. 38 CFR Part 16, Protection of Human Subjects
10. 38 CFR Part 17, Medical